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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| In re Application of: |) | |
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| •• | : | Examiner: L. Wong |
| PONAKALA ET. AL. |) | |
| | : | Group Art Unit: 1761 |
| Application No.: 09/465,402 |) | |
| | : | • |
| Filed: December 17, 1999 |) | |
| | : | |
| For: N-[N-(3,3-DIMETHYLBUTYL)-1- α - |) | |
| ASPARTYL]-L-PHENYLALANINE 1- | : | August 27, 2001 |
| METHYL ESTER AS A SWEETENER IN | | |

Assistant Commissioner for Patents Washington, D.C. 20231

CHEWING GUM

RESPONSE

Sir:

I. Applicants petition to extend the time for response to the Office Action dated March 27, 2001, for two months from June 27, 2001, to August 27, 2001. Please deduct the \$390.00 extension fee from Deposit Account 14-1451. Please charge any additional fee required for the extension, and credit any overpayment, to Deposit Account 14-1451.

II. This is in response to the Office action mailed March 27, 2001, in the aboveidentified case. The claims presently in the pending application are claims 1-53, with claims 1 and 28 being independent.

Claims 1-53 stand rejected under 35 U.S.C. 103(a) as allegedly unpatentable over C LOS CONTRACTOR OF THE PARTY O U.S. Patent 5,480,668 issued Nofre et al.

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Remarks

Claims 1-53 stand rejected under 35 U.S.C. 103(a) as unpatentable over Nofre et al. Applicants respectfully traverse the rejection. Applicants acknowledge Nofre discloses that N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester is an extremely potent sweetening agent that can be used by itself or in combination with other sweetening ingredients in a variety of products. However, Nofre et al. does not disclose or suggest the unexpected and advantageous results of using N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester in chewing gum formulations, specifically, the prolongation of sweetness and flavor perception. Applicants therefore contend that one skilled in the art would not be motivated to modify the Nofre et al. disclosure to achieve the such benefits in chewing gum formulations.

Applicants also acknowledge that the use of various sweeteners in chewing gum formulations, in particular, the use of aspartame, is well known in the art. Applicants contend, however, that one of ordinary skill in the art would recognize the challenges and difficulties of sweetening chewing gum formulations with aspartame and conclude that these same challenges and difficulties also would be presented by N-[N-(3,3dimethylbutyl)-L- α -aspartyl]-L-phenylalanine methyl ester. Over the past 10-15 years, the challenges and difficulties of using aspartame are readily apparent based on the number of disclosures directed to the sweetening of chewing gum formulations. Many of these disclosures have been incorporated as references in the present application and provided in the Information Disclosure Statement. The challenges and difficulties of using aspartame in chewing gum formulations stem from its inability to remain in the gum base during chewing. Many of the disclosures attempt to solve this problem by incorporating aspartame within the gum base in some fashion so as to provide a controlled release of sweetness. Aspartame is typically not used alone, but rather with some modifying agent or some other method of incorporation to control its release. Thus, there would be reason why one of ordinary skill in the art would have predicted that the same challenge and difficulty of controlled release presented by aspartame would be overcome by using N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester. On the contrary, use of N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine methyl ester provides not only sweetness in chewing gum formulations without the need

for modifying agents or special incorporation within the gum base, but also provides sweetness prolongation compared to other high-intensity sweeteners. Applicants request that the examiner reconsider the rejection of claims based on the unexpected and advantageous results provided by N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester in chewing gum formulations, as described in detail in the present application.

Applicants respectfully request that the examiner review the written description of the embodiments; the examples with corresponding Figures and Tables; and the claims of the present application. Clearly, the sweetness intensity of chewing gum prepared with N- $[N-(3,3-dimethylbutyl)-L-\alpha-aspartyl]-L-phenylalanine methyl ester is significantly$ greater after the time of chewing than the other sweeteners tested (FIG. 1). This unique characteristic of N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester is specifically claimed in Claims 19-20, and Claim 46. Flavor prolongation and the related property of flavor sparing also are provided by N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester (FIG. 2). This is another advantageous characteristic of using N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine methyl ester in chewing gums and is specifically claimed in Claims 21-22, and Claims 47-48. Chewing gums prepared with N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine methyl ester also exhibit surprising flavor and sweetness balance (FIG. 3 and FIG. 4). A detailed description of these properties and how these advantages can be used in chewing gum formulations is illustrated in the present application. Said properties of using N-[N-(3,3dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester in chewing gum are both unexpected in view of the related art in general, and in view of Nofre et al. in particular. Applicants stress that Nofre et al. could not have recognized such unique properties of N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester in chewing gum formulations without undue sensory experimentation. One of ordinary skill in the art also would not recognize these properties of N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-Lphenylalanine methyl ester since the art does not disclose or suggest such characteristics.

Another advantage N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine methyl ester provides chewing gum formulations is the ability to use a rapid release

sweetener such as sucrose in the formulation. Thus, a combination of N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine methyl ester and sucrose provides both an immediate impact of sweetness and sweetness extension. The immediate and extended sweetness perception in chewing gum is previously unknown in the art and can only be realized by using N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine methyl ester. Claims directed to the unique advantage of using a rapid release sweetener and N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine methyl ester are Claims 23-25 and Claims 49-51.

Applicants further contend that Nofre et al. does not provide the motivation for extending the shelf-life stability of N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-Lphenylalanine methyl ester in a chewing gum formulation. The present invention provides chewing gum compositions and methods for producing said compositions wherein N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester is encapsulated or co-dried with suitable chewing gum components in order to extend its shelf-life stability. The encapsulated or co-dried forms of N-[N-(3,3-dimethylbutyl)-L-αaspartyl]-L-phenylalanine methyl ester provide protection of N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester from chewing gum components that may interact with N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester over time. As a consequence, N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester in an encapsulated or co-dried form is rendered more stable. The disclosure particularly points out the stability enhancements provided by a variety of agents when used as vehicles to either encapsulate or form a co-dried admixture with N-[N-(3,3dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester. Claims directed towards increasing the shelf-life stability of N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-Lphenylalanine methyl ester are Claims 26-27, and Claims 52-53.

Based on the review of the technical merits of the present invention, Applicants respectfully request that the Examiner reconsider the pending claims in view of the unexpected and surprising results provided by N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester, as reiterated above. Even if the Examiner doesn't accept Applicants arguments regarding the broadest claims, claims specific to the unique and

characteristic properties provided by N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine methyl ester in chewing gum formulations should be allowed. Applicants wish to point out that the Examiner has not presented any argument to such claims, specifically, those claims directed to sweetness extension (Claims 19-20, 46), those claiming flavor extension and flavor sparing (Claims 21-22, 47-48), those claiming use of N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine methyl ester with a rapid release sweetener (Claims 23-25, 49-51), and those claiming an increase in shelf-life stability (Claims 26-27, 52-53).

In conclusion, Applicants respectfully submit that Nofre et al. does not disclose or suggest the presently claimed invention. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejections set forth in this Office Action, and earnestly solicit allowance of the claims now pending in the subject application.

Respectfully submitted,

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Date: August 27, 2001